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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/663,794

09/17/2003

Ming-Hui Wei

CL001164CIP-DIV. II

3773

25748

7590

11/13/2006

EXAMINER

HUMPHREY, DAVID HAROLD

CELERA GENOMICS

ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY

45 WEST GUDE DRIVE

C2-4#20

ROCKVILLE, MD 20850

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,794

Applicant(s)

WEI ET AL.

Examiner

David Humphrey

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 12 and 24-39 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 27-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/08/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Claims 3, 12, and 24-39, are pending.

Claims 12, and 24-26, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Claims 3, and 27-39, are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections

Specification

3. The objection to the specification for failing to contain the updated status of all parent priority applications in the first line of the specification is withdrawn due to Applicants' arguments that the updated status is included in the Application data sheet.
4. The objection to the disclosure for containing an embedded hyperlink and/or other form of browser-executable code is withdrawn due to Applicants' amendment to the specification.

Maintained Rejections

Claim Rejections - 35 USC § 102

5. The rejection of claims 3, and 27-39, under 35 U.S.C. §102(e) as being anticipated by Yue et al. (WO 01/96547 A2; International Filing Date 14 June 2001; effective filing date 30 June 2000) is maintained.

Applicants argue that for the antibody of Yue et al. to anticipate the instant claims, the antibody of Yue et al. must necessarily selectively bind to the polypeptides recited in the instant claims, i.e. polypeptides comprising or consisting of SEQ ID NO: 2. Applicants further argue that the Examiner has cited a reference that teaches an antibody that may possibly or probably selectively bind to polypeptides of SEQ ID NO: 2 because the reference antibodies bind to a protein that has an amino acid sequence that is partially identical to SEQ ID NO: 2 without demonstrating that the reference antibodies must necessarily selectively bind to polypeptides of SEQ ID NO: 2, see Remarks, page 4, 4th full paragraph, lines 2-6. Applicants additionally argue that the antibody of Yue et al. does not selectively bind to polypeptides of SEQ ID NO: 2 because significantly different epitopes must necessarily exist in the polypeptide of SEQ ID NO: 2 compared with the PKIN protein of Yue et al. because of the extensive differences that exist in their amino acid sequences. Applicants state that the amino acid sequence of SEQ ID NO: 2 differs from the PKIN protein of Yue et al. by not only the five amino acids at the C-terminus of SEQ ID NO: 2 but also the additional 241 amino acids that are present in the PKIN protein of Yue et al. that are not present in SEQ ID NO: 2, see Remarks, page 4, bridging sentence to page 5. Therefore, these

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regions would constitute protein epitopes that present in one protein but not the other. Applicants conclude that due to the structural differences in the protein structure of the PKIN protein of Yue et al. and SEQ ID NO: 2, the antibody of Yue et al. does not necessarily cross-react and selectively bind to the same proteins as the antibodies of instant claims.

Applicant's arguments have been carefully considered but found not persuasive. Yue et al. teach an isolated antibody that selectively binds to a polypeptide called PKIN (a human kinase protein; SEQ ID NO: 7), which is 100% sequence identical to claimed SEQ ID NO: 2, over amino acids 1-252 and 98% overall (amino acids 1-257). Therefore, any antigenic epitopes of SEQ ID NO: 2 in amino acids 1-252 would be similarly included in the PKIN polypeptide. The only portion of SEQ ID NO: 2 not contained within the PKIN polypeptide is amino acids 253-257. Applicants have not disclosed any antigenic portions or epitopes that are contained within claimed SEQ ID NO: 2. In addition, Applicants have not disclosed that amino acids 253-257 comprise an antigenic portion that may serve to distinguish the instant antibodies. Therefore, the argument about epitope differences between SEQ ID NO: 2 and PKIN protein is merely speculative in nature. The Examiner acknowledges that amino acids 253-497 of PKIN are different from SEQ ID NO: 2 and thus antibodies raised against those portions of PKIN would not bind to SEQ ID NO: 2. However, it is the Examiner's position that any polyclonal or monoclonal antibodies raised using SEQ ID NO: 2, which is 98% identical to PKIN, would cross-react with PKIN protein of Yue et al. Therefore, the claimed

antibodies would not selectively bind the polypeptide of SEQ ID NO: 2 and are anticipated Yue et al.

6. The rejection of claims 3, and 27-39, under 35 U.S.C. §102(e) as being anticipated by Yu et al. (United States Patent Application Publication 2002/0123622; effective filing date 12/27/2000) is maintained.

Applicants argue that for the antibody of Yu et al. to anticipate the instant claims, the antibody of Yu et al. must necessarily selectively bind to the polypeptides recited in the instant claims, i.e. polypeptides comprising or consisting of SEQ ID NO: 2. Applicants further argue that the Examiner has cited a reference that teaches an antibody that may possibly or probably selectively bind to polypeptides of SEQ ID NO: 2 because the reference antibodies bind to a protein that has an amino acid sequence that is partially identical to SEQ ID NO: 2 without demonstrating that the reference antibodies must necessarily selectively bind to polypeptides of SEQ ID NO: 2, see Remarks, page 6, bridging sentence to page 7. Applicants additionally argue that the antibody of Yu et al. does not selectively bind to polypeptides of SEQ ID NO: 2 because significantly different epitopes must necessarily exist in the polypeptide of SEQ ID NO: 2 compared with the NHP protein of Yu et al. because of the extensive differences that exist in their amino acid sequences. Applicants state that the amino acid sequence of SEQ ID NO: 2 differs from the NHP protein of Yue et al. by not only the five amino acids at the C-terminus of SEQ ID NO: 2 but also the additional 1702 amino acids that are present in the NHP protein of Yu et al. that are not present in SEQ ID NO: 2, see

Remarks, page 7, 1st full paragraph, lines 4-9. Therefore, these regions would constitute protein epitopes that present in one protein but not the other. Applicants conclude that due to the structural differences in the protein structure of the NHP protein of Yu et al. and SEQ ID NO: 2, the antibody of Yu et al. does not necessarily cross-react and selectively bind to the same proteins as the antibodies of instant claims.

Applicants' arguments have been carefully considered but found not persuasive. Yu et al. teach an isolated antibody that selectively binds to a polypeptide called NHP (novel human protein with structural similarity to serine-threonine kinases, particularly Citron rho-interacting kinases, see page 1, paragraph 4, lines 1-8; page 8, paragraph 73, lines 1-4; SEQ ID NO: 4), which is 100% sequence identical to claimed SEQ ID NO: 2, over amino acids 1-252 and 98% overall (amino acids 1-257). Therefore, any antigenic epitopes of SEQ ID NO: 2 in amino acids 1-252 would be similarly included in the NHP polypeptide. The only portion of SEQ ID NO: 2 not contained within the NHP polypeptide is amino acids 253-257. Applicants have not disclosed any antigenic portions or epitopes that are contained within claimed SEQ ID NO: 2. In addition, Applicants have not disclosed that amino acids 253-257 comprise an antigenic portion that may serve to distinguish the instant antibodies. Therefore, the argument about epitope differences between SEQ ID NO: 2 and NHP protein is merely speculative in nature. The Examiner acknowledges that amino acids 253-1958 of NHP are different from SEQ ID NO: 2 and thus antibodies raised against those portions of NHP would not bind to SEQ ID NO: 2. However, it is the Examiner's position that any polyclonal or monoclonal antibodies raised using SEQ ID NO: 2, which is 98% identical to NHP,

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would cross-react with NHP protein of Yu et al. Therefore, the claimed antibodies would not selectively bind the polypeptide of SEQ ID NO: 2 and are anticipated Yu et al.

Conclusion

7. No claim is allowed.

8. No new grounds of rejection were presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Humphrey, Ph.D.

November 3, 2006



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER